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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,914	12/28/2001	Yoshihide Murakami	Q67950	2679

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SUGHRUE MION, PLLC
2100 Pennsylvania Avenue, NW
Washington, DC 20037-3213

EXAMINER

CHANG, VICTOR S

ART UNIT	PAPER NUMBER
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1771

DATE MAILED: 08/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/028,914

Applicant(s)

MURAKAMI ET AL.

Examiner

Victor S. Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2005.
2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 17 and 18 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-9, 17 and 18 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Introduction

1. The Examiner has carefully considered Applicants' amendments and remarks filed on 7/14/2005. Applicants' amendment to claim 1 has been entered. Also, a correction of typo to claim 7 is noted.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Rejections not maintained are withdrawn.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-9, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, it is noted that independent claim 1 has been substantially amended to recite, *inter alia*, "A single layer substrate film ... consisting essentially of ... wherein the single layer substrate has a tensile modulus of elasticity in a saturated water absorption state lower as compared to a tensile modulus in a dry state such that when the substrate is in combination with the adhesive sheet and the adhesive sheet is adhered to skin, the tensile modulus of elasticity of the substrate film decreases, which

improves the flexibility and skin follow-up property of the adhesive sheet". The Examiner notes that such an amendment renders the instantly claimed invention vague and indefinite, since it is no longer clear whether a "single layer substrate film" is being claimed, or some combination of it with "an adhesive sheet and the adhesive sheet is adhered to skin" is being claimed. Clarification is requested.

Rejections Based on Prior Art

6. Claims 1-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bezwada et al. (US 5607687), generally as set forth in section 5 of Office action dated 4/14/2005, together with the following additional reasoning and response to argument.

For the purpose of clarification, the Examiner repeats the relied upon prior art as follows: For claims 1-9, Bezwada's invention is directed to a bioabsorbable polymeric material and blends thereof and more particularly to absorbable surgical products made from such polymers and blends thereof (column 1, lines 11-14). The blends comprises polyether polyurethanes, polyester polyurethanes, polyvinyl pyrrolidone, etc., and combinations thereof (column 2, lines 17-67). Useful embodiments made of the polymer blend include sheets for areas where the skin and underlying tissues are damaged or surgically removed, i.e., wound dressing (column 6, lines 38-64).

With respect to the newly added limitation "wherein the single layer substrate has a tensile modulus of elasticity in a saturated water absorption state lower as compared to a tensile modulus in a dry state", the Examiner notes that while Bezwada is silent

about the tensile moduli of his absorbable film in water saturated state and dry state, since Bezwada does teaches a film having the same elastomer resins and hydrophilic polymer as claimed, it is the Examiner's position that, in the absence of evidence to the contrary, the relative strength of the tensile moduli of the absorbable film in water saturated state and dry state is either anticipated by Bezwada, or obviously provided once the same polymers are selected.

Applicants' arguments "Applicants limit the claims by the use of "consisting essentially of" language ... the single layer substrate film ... is now limited to the recited components and excludes the presence of components would alter the basic and novel characteristics of the single layer substrate or the adhesive sheet ... Bezwada discloses polymer blends comprising a polyoxaester as a main component ... shows bioabsorbable properties" (Remarks, pages 4-5, bridging paragraph; and page 5, bottom paragraph) have been carefully considered, but are not persuasive. First, the Examiner notes that Bezwada's polyoxaester also reads on the element "hydrophilic polymer" of claim 1. Second, Applicants have failed to identify what basic and novel characteristics of claimed invention would be materially affected by polyoxaester, as such it is not seen how the phrase "consisting essentially of" is to narrow the claim scope to exclude Bezwada. The Examiner maintains that each element claimed instantly is found in the art of Bezwada and no additional features are required thereby, even if one were to hold "consisting essentially of" as limiting. In other words, the instantly claimed invention fails to preclude the teachings of Bezwada, Applicants' argument to the contrary notwithstanding.

With respect to Applicants' argument "A bioabsorbable adhesive sheet would, in a short period of time, turn out to be useless for purpose of the present invention", the Examiner respectfully reminds Applicants that, in the absence of factual support, attorney's argument cannot take place of evidence, and there is not any functional language present in the claims to limit such to any particular utility such that the products of Bezwada would be unable of performing.

With respect to Applicants' argument "the products of the present invention are not bioabsorbable ... the products claimed and the Bezwada products cannot be identical or substantially identical in structure or composition" (Remarks, page 7, top paragraph), the Examiner respectfully reminds Applicants that the preamble of independent claim 1 merely recites "A single layer substrate film" and nowhere is there an recitation in any claim limits the scope of instant invention as "not bioabsorbable". Applicants' argument is without merit to the present rejection.

With respect to Applicants' argument "Applicants ... have now correlated "for an adhesive sheet" in the preamble with the portion of the claim following the preamble, and thus the language now used in the preamble should be attached patentable weight" (Remarks, page 7, 3rd paragraph), the Examiner notes that since the preamble of independent claim 1 is not directed to a combination of "a substrate film and an adhesive sheet, and the adhesive sheet is adhered to skin", even the "wherein ..." clause also recites how the substrate film is applied to skin, it does not contribute to the structure of the device set forth in the preamble, and fails to attach patentable weight,

Applicants' argument to the contrary notwithstanding, especially since the applied art is capable of receiving an adhesive layer, even if such were not taught.

7. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bezwada et al. (US 5607687) in view of Webster (US 4541426), generally as set forth in section 6 of Office action dated 4/14/2005, together with the following additional reasoning and response to argument.

With respect to Applicants' argument "what is lacking is motivation to combine Bezwada and Webster" (Remarks, page 8), the Examiner repeats that Webster's invention is directed to a dressing suitable for application to lesions of the skin (i.e., wound dressing), which is inherently a bioabsorbable material, as such they are clearly directed to the same field of endeavor, and their teachings are combinable, Applicants' argument to the contrary notwithstanding.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor S. Chang whose telephone number is 571-272-1474. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel H. Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VSC

Victor S Chang
Examiner
Art Unit 1771

8/8/2005


TERREL MORRIS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700